



The Influence of Different Connecting Rod Configurations on the Stability of the Ilizarov Frame: A Biomechanical Study

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Declaration

I, *Dr Gerhard Thiar*, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

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Abstract

Background

The Ilizarov external fixator (IEF) is frequently used in trauma and elective orthopaedics. Many of its biomechanical variables (ring size; wire diameter; wire number; half pins versus wires; etc.) and their influence on stability and stiffness have been investigated. There is however a paucity in the literature regarding the influence of the connecting rod numbers and configurations between the rings on IEF stability.

Objectives

Primarily to compare the stability between four and three rod IEF configurations. Secondly to assess the difference in stability between symmetrical and asymmetrical spacing of the IEF rods.

Methods

A custom jig was designed to facilitate mounting of a basic two ring IEF in a hydraulic press. Controlled centre and off centre (thus simulated bending) axial loading was then applied across the frame. The configurations were loaded up to 4000 Newtons. The frame deformation was plotted and the data was then analysed and interpreted.

Results

Negligible differences were observed between different four and three rod configurations as long as the applied force at the loading point (LP) was within the area of support (AOS) created by the rods. The different four rod constructs were always more stable than the three rod constructs during bending.

Conclusions

There is comparable stiffness between a four rod and a three rod IEF construct as long as the loading point (LP) is within the area of support (AOS) created by the rods. A four rod IEF is stiffer than a three rod IEF in bending.

Key Words

Ilizarov; Stability; Stiffness; Connecting Rods

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Abbreviations

AOS	Area of support
IEF	Ilizarov external fixator
LP	Loading point
N	Newton
Nm	Newton meter
POP	Plaster of Paris
TSF	Taylor Spatial Frame

PART A

LITERATURE REVIEW

LITERATURE REVIEW

INTRODUCTION

The Ilizarov frame was first developed by Professor Gavriil Abramovich Ilizarov during the 1950's(41). It is a circular type external fixator used to stabilise any bony disruption (e.g. fracture following trauma or an osteotomy following an elective orthopaedic procedure) using a minimally invasive method. The frame consists of circular rings, connected to each other by a number of rods, length stable or telescopic, to form a "tube" around the affected limb it is applied upon (19, 39). The rings are affixed to the bone of the limb segment by using thin smooth wires or threaded half pins. Thus, the bone fragments are transfixed in space in relationship to each other with minimal movement allowed, thus creating the optimal environment for bone healing and union (15).

The interaction of all the mechanical forces involved (within the Ilizarov frame and between the Ilizarov frame and the bone) influence bone healing. Due to the biomechanical complexity, numerous studies have been undertaken to investigate the different aspects (or parameters) of it.

OBJECTIVES

- To determine what different mechanical force vectors influence bone healing
- To determine which of these forces are addressed by the Ilizarov apparatus (frame)
- To understand the different components of the Ilizarov apparatus and how they influences the forces in question
- To identify which of these components have been studied and the potential deficits for further research.

LITERATURE SEARCH STRATEGY, INCLUDING INCLUSION AND EXCLUSION CRITERIA

A Google Scholar and PubMed search was done for any recent Ilizarov biomechanical studies using the terms “Ilizarov” and “stability”. References from recent publications were identified and scrutinised. Appropriate chapters in dedicated textbooks on the subject were also used. Thus, the classic and landmark papers published by investigators in this field over the last few decades were identified.

A literature review on bone healing was also performed to correlate the biomechanics of the Ilizarov frame and its influence on bone union. This was to provide a better understanding of bone healing, parameters involved and the influence of different mechanical force vectors on healing.

Lastly, the gathered research was summarized to see which parameters of the Ilizarov frame and its influence on bone healing have been investigated and where opportunities for further research lie.

The reference articles were grouped (see table one and two below) as those investigating *bone healing* and those investigating Ilizarov *frame parameters*. Although the focus pertained to *circular* fixation, a lot of the early research involving bone healing used *uniplanar* type fixators. Some of these studies were also included to gain insight into mechanical forces influencing bone healing and not so much for those specific external fixators and their parameters. Excluded research were articles that reported on uniplanar external fixators alone and the parameters influencing their stability.

The reference articles gathered span a period from 1964 to 2014. They are mostly of a biomechanical nature (Level 5 evidence, using the 2011 Oxford CEBM Levels).

Table 1 – Literature articles used to summarise Ilizarov frame parameters (*refer to the references section for more complete details*)

AUTHOR	YEAR	ARTICLE TITLE
Aronson	1992	Mechanical Considerations in Using Tensioned Wires in a Transosseous External Fixation System(1)
Bronson	1998	Stability of external circular fixation: a multi-variable biomechanical analysis(3)
Caja	1995	Comparison of the mechanical performance of three types of external fixators - linear, circular and hybrid(4)
Calhoun	1992	Biomechanics of the Ilizarov Fixator for Fracture Fixation(6)
Calhoun	1991	Rigidity of half-pins for the Ilizarov external fixator(5)
Cross	2001	Effects of ring diameter and wire tension on the axial biomechanics of four-ring circular external skeletal fixator constructs(9)
Davidson	2003	Ilizarov wire tensioning and holding methods: a biomechanical study(10)
Duda	2000	Mechanisches Verhalten von Ilizarov-Ringfixateuren(13)
Fleming	1989	A Biomechanical Analysis of the Ilizarov External Fixator(14)
Gasser	1990	Stiffness Characteristics of the circular Ilazrov device as opposed to conventional external fixators(17)
Gessmann	2012	Improved wire stiffness with modified connection bolts in Ilizarov external frames: a biomechanical study(18)
Goodship	1993	The Role of Fixator Frame Stiffness in the Control of Fracture Healing - An Experimental Study(21)
Kummer	1992	Biomechanics of the Ilizarov External Fixator(28)
La Russa	2010	Wire tension versus wire frequency: An experimental Ilizarov frame study(29)
Mullins	2003	The biomechanics of wire fixation in the Ilizarov system(32)
Podolsky	1993	Mechanical Performance of Ilizarov Circular External Fixator in Comparison With Other External Fixators(37)

Roberts	2005	The effect of transfixion wire crossing angle on the stiffness of fine wire external fixation: A biomechanical study(38)
Spiegelberg	2010	Ilizarov principles of deformity correction(41)
Tan	2014	A Biomechanical Comparison between Taylor's Spatial Frame and Ilizarov External Fixator(42)
Zhang	2004	Avoiding the material nonlinearity in an external fixation device(43)

Table 2 – Literature articles used to summarise bone healing (*refer to the references section for more complete details*)

AUTHOR	YEAR	ARTICLE TITLE
Cheal	1991	Role of interfragmentary strain in fracture healing - Ovine model of a healing osteotomy(7)
Claes	1998	Effects of Mechanical Factors on the Fracture Healing Process(8)
De Bastiani	1984	The Treatment of Fractures with a Dynamic Axial Fixator(11)
DiGioia	1986	Three-Dimensional Strain Fields in a Uniform Osteotomy Gap(12)
Fleming	1989	A Biomechanical Analysis of the Ilizarov External Fixator(14)
Gardner	1996	The influence of external fixators on fracture motion during simulated walking(16)
Goodship	1998	Strain rate and timing of stimulation in mechanical modulation of fracture healing(22)
Goodship	1985	The Influence of induced micromovement upon the healing of experimental tibial fractures(20)
Harwood	2010	An update on fracture healing and non-union(23)
Ilizarov	1989	The tension-stress effect on the genesis and growth of tissues. Part I. The influence of stability of fixation and soft-tissue preservation(24)
Ilizarov	1989	The Tension-Stress Effect on the Genesis and Growth of Tissues: Part II. The Influence of the Rate and Frequency of Distraction(25)
Jagodzinski	2007	Effect of mechanical stability on fracture healing an update(27)
Marsell	2011	The Biology of Fracture Healing(31)
Park	1998	The Influence of Active Shear or Compressive Motion on Fracture-Healing(33)
Perren	2002	Evolution of the Internal Fixation of Long Bone Fractures(36)
Perren	1980	The Concept of Inter Fragmentary Strain(35)
Perren	1979	Physical an biological aspects of fracture healing with special reference to internal fixation(34)

SUMMARY OF THE LITERATURE

Background

Professor Gavriil Abramovich Ilizarov was a Russian physician turned surgeon that was practising his skills in the city called Kurgan from the 1950's onwards (39, 41). He developed the concept of a circular external fixator between 1950 and 1954 to overcome the problems of delayed and non-union seen mostly in military veterans returning from World War 2 with mangled limbs. Internal fixation of fractures (using plating techniques) had problems with sepsis due to a shortage of antibiotics. Plaster of Paris (POP) or prolonged traction in bed also failed to achieve desired results. He treated his first patient, a metalworker, from the factory that manufactured his apparatus. Due to politics in the Russian medical field, Ilizarov's apparatus wasn't accepted as the gold standard of care (in Russia) until after 1985.

Ilizarov achieved recognition in 1968 when he successfully treated Valery Brumel, a gold medal high jump Russian Olympian athlete, who sustained a distal tibia fracture. He was unsuccessfully treated by numerous surgeons, but after being treated with Ilizarov's apparatus his infected non-union united. His second claim to fame, and final breakthrough internationally, was with the successful treatment of Carlo Mauri, an internationally well-known Italian photographer, explorer and alpinist. He was living with a non-union for years which, after hearing of Ilizarov and traveling to him in Kurgan in 1980, was treated to union. He wrote an article titled "Michelangelo of Orthopaedics" which really introduced Ilizarov's apparatus to the West. Due to this he was invited to present at the 22nd Italian AO conference in Bellagio, Italy, in 1981. This was the first time Ilizarov had a chance to present his findings and apparatus to a medical community outside of Russia. This led to further international exposure with resulting American Orthopaedic surgeons visiting Kurgan in 1987. What followed was Ilizarov's first lecture at the New York Hospital for Joint Diseases which cemented the usage of the Ilizarov apparatus in western medicine.

Ilizarov performed numerous studies on animals to investigate and proof his ideas. Of his papers, only three were ever published in English. These are considered landmark papers(2) and were titled "*The Tension-Stress Effect on the Genesis and Growth of Tissues Part I: The Influence of Stability of Fixation and Soft-Tissue Preservation*"(24), "*The Tension-Stress Effect on the Genesis and Growth of Tissues Part II: The Influence of the Rate and Frequency of Distraction*"(25) and "*Clinical application of the Tension-stress Effect for Limb Lengthening*"(26). Here in he demonstrated distraction osteogenesis as well the optimal rate of distraction, being one millimetre per day.

He also coined the term “the Law of Tension–Stress” after realizing that it wasn’t only bone tissue that regenerated with distraction, but also blood vessels, nerves, skin, etc.(39)

Ilizarov’s frame revolutionized the approach to traumatic long bone fractures. With his apparatus applied to traumatic non-unions he managed to reduce the time of morbidity three to five fold. In the case of open fractures the morbidity times were even reduced eight-fold.

Mechanical Aspects of Ilizarov’s apparatus (Frame)

The base parts of the frame consist of circular rings connected to each other by rods. The rings may be either fully circular (closed), partial (open) or arch (half rings). The original Ilizarov rings were made of medical grade stainless steel. Newer rings are made from Aluminium alloy. The rods are usually six millimetre threaded medical grade stainless steel. They may also come in tubular or telescopic variants. The rods are tightened with nuts to the rings. The frame is attached to the bone segment by means of wires and/or half pins. The wires may be of varying thickness (ranging from 1.2 to 2.0 millimetres) and materials (cobalt; titanium; etc.). The wires can be smooth or have a thickening within its length, called an olive, to provide the user with a pulling force. The wires are transfixed, through the bone segment, to both sides of the ring. So, it will always have two ring-wire interfaces or fixation points. The wires are fixed, after being pre-tensioned, to the ring with a special bolt, called a wire fixation bolt. These differ in design and work in different ways as to how they fix the wire to the ring. The half pins are threaded, usually five to six millimetres in diameter and are only attached to the ring at one point. Thus, a half pin will pierce the skin, underlying soft tissue and then both cortices of the bone, but won’t protrude out the opposite skin and attach again to the ring like a wire. The half pins may also be coated with hydroxyapatite to enhance the bone-pin interface to help reduce pin loosening. These form the base parts of the Ilizarov frame.

The way, or configuration, in which these parts are applied will ultimately determine the frame stability(28). A basic guideline was provided by Ilizarov’s daughter in her published textbook(39). It follows the “Rule of Twos” mantra:

- 2 centimetres between skin and frame
- 2 rings per bone segment
- 2 point of fixation per ring
- 2 x 2 (thus 4) connecting rods between rings

- Both ends (thus 2) of the bone segment must be stabilized - the “near and far” principle
- 2 planes of fixation per ring

Frame stiffness is of paramount importance (see section on bone healing). As Kummer et al(28) put in his article *“stability is the ability of the fixator to maintain the necessary mechanical configuration during treatment; Rigidity is a measure of the mechanical response of the fixator, which has importance in the healing response. For all fixators, the desired aim is to achieve a stable frame (in general, rigid) and pin configuration coexistent with the specific requirements and limitations of the clinical situation.”* Depending on the fracture pattern, amount of bone segments that need to be stabilized, soft tissue injury/involvement and surgeon preference the final frame construct may be very complex. Thus it can be seen that there are numerous parameters that can be adjusted and all those parameters have a certain impact on the frame's final stability and stiffness(3). Over the course of the last few decades since Ilizarov introduced his frame to western medicine a lot of research has been conducted on the individual components. But before these studies are summarized, the physiology of fracture healing has to be reviewed to understand why frame stability is so important.

Short Synopsis of Bone Healing

Bone heals by one of two mechanisms: Direct bone healing or indirect bone healing(31).

Direct bone healing occurs where the fracture ends are compressed together and form a stable construct after reduction. It can be compressed together by whatever mechanism the treating clinician thinks is appropriate. The final part of the fracture healing process (the ossification) can only occur if the bone ends are stable enough. In the process of direct bone healing, where the fracture ends are stabilised by the compressive effect, the body doesn't need to utilise its own natural stabilisation processes. The former process being the production of soft callous that fills the fracture gap to reduce the fracture site motion to such a degree that the callous can be ossified to a hard callous and then final bone union(16). Thus, healing is by means of remodelling of lamellar bone. Direct bone healing can be further subdivided into contact healing (fracture gap less than 0.02 millimetres and strain less than two percent) or gap healing (fracture gap of 0.8 to 1 millimetre)(31). Direct bone healing is an unnatural process which is only possible due to surgical intervention with absolute stability.

Indirect bone healing is the body's natural way to complete bone union. It consists of a combination of enchondral and intramembranous healing processes. As explained above the body needs to stabilise the fracture first and reduce the amount of motion to the next tolerable level so that the natural next

step in healing can occur. If this process is halted anywhere along its course, then a situation ranging from an atrophic non-union up to a fibrous filled fracture non-union (pseudarthrosis) can be the result. Any non-surgical (e.g. Plaster of Paris) or surgical (e.g. bridge plating, intramedullary nailing, external fixators) system that indirectly controls the fracture ends will lead to the process of indirect bone healing. Any fracture pattern that is not anatomically reducible, will lead to indirect bone healing.

A lot of research has been conducted to try and understand bone healing and how to manipulate it by either biological or mechanical means. With the Ilizarov frame being (mostly) a system of indirect stabilisation (See in the next section that an Ilizarov frame can also be utilised as a compressive, and thus direct stabilisation, device) the need to understand the interplay between the different force vectors (e.g. longitudinal/axial; translational/shear; rotational/torsion; bending) and fracture gap distance are of great importance(23). Perren et al suggested the interfragmentary strain hypothesis (or theory)(34). This hypothesis predicts that the level of strain at the fracture site will produce specific tissue that can tolerate that strain. As Perren stated in his article from 2002(36): *"The absence of dynamic relative deformation results in lack of mechanical induction of callus formation. Very small amounts of strain induce callus formation. Strain values up to 2% are tolerated by lamellar bone tissue, up to 10% are tolerated by the three-dimensional configuration of woven bone and between 10% and 30% induction of resorption prevails."* His theory only addressed longitudinal/axial forces. It did guide future research though. Goodship et al demonstrated that axial motion enhances callus formation(20). Later Claes et al found if the fracture gap is less than 2 millimetres and the longitudinal amplitude of movement is between 0.2 to 1 millimetre then indirect bone healing will be optimal(8). But this has been found to be true for the early phase of indirect bone healing. Later on, when the strain needs to be less, to induce ossification (hard callous), this amount of movement is actually detrimental(22, 27). There is still uncertainty of whether compressive or distractive axial force vectors are more advantageous to this healing process(27). Regarding the other force vectors, there is uncertainty about the effect of shear across the fracture gap(23). Some investigators still see this as detrimental to healing(14), but Park et al have found evidence contradictory to this(33). Harwood summarizes as follows: *"Uni-axial micromotion appears to stimulate bone healing to a point, with off-axis motion inhibiting this. The potential effect of bending or torsional loading is even less clear. Torsion is likely to create rotational shear. Bending will lead to large differential compressive and tensile loads across the cross section of the fracture. Both these situations are likely to be unfavourable."*(23)

All the different force vectors seem to influence tissue in a different way. Fibroblasts are stimulated by tension, chondroblasts by shear and osteoblasts by compression and distraction(23). Thus, for any mechanical system applied that induces indirect bone healing, it should allow for minimal disturbance at the fracture site (to maintain maximum perfusion), facilitate sufficient micromotion during the early phase of healing, maintain axial, rotational, bending and translational force vectors adequately, and then in the final phase of healing limit micromotion(27). All of this can be accomplished with an Ilizarov frame, but due to the complexity of the frame and its almost limitless number of adjustable

variables each constructed frame has a slightly different amount of control over the discussed force vectors.

Summary of investigations on the individual Ilizarov frame components and their influence on stability.

i) Wires

Probably the most intensely investigated component of the Ilizarov frame. Parameters to consider are:

Material type

Wire Type

Thickness

Amount of pre-tension to be applied

Number of wires to use

The planes the wire needs to be in

The angles at which the wires need to intersect

Regarding the material type it has been shown that Cobalt wires are stiffer than Titanium wires due to less plastic deformation/elongation(13).

Calhoun et al found that using olive wires also increased frame stiffness(6).

Thicker wires deliver more frame stiffness and thus 1.8 millimetre wires are preferred where possible(13, 37, 41).

It was shown by increasing the number of wires will also increase frame stiffness(6, 13, 41).

Furthermore, Duda et al advises that thicker wires be used as opposed to increasing the number of wires as this will lead to potentially less complications (e.g. neurovascular injury)(13).

Pre-tension has been investigated or commented on by numerous authors. Zhang et al described the interplay between geometric and material nonlinearity. By increasing wire pre-tension, it will also lead to a stiffer frame construct (geometric nonlinearity; specifically related to axial stiffness) but up to a point. If the pretension is too much it will lead to loss of wire elasticity (material nonlinearity) and

cause plastic deformation (e.g. lengthening) with resulting loss of stiffness(43). La Russa et al came up with a formula considering wire frequency as an indicator of stiffness, but stresses that this may only be used in vitro(29). Fleming et al showed that increased wire pre-tension increased axial and bending stiffness but decreased torsional stiffness(14). Caja et al also commented on the importance of correct wire tension(4). Podolsky et al found in his study that wire pre-tension had a direct relation to frame stiffness(37). Aronson et al produced an excellent paper on wire tension and the factors that influence it. From his work wire tension loss was postulated to either due to plastic deformation, warping of the rings or slippage at the wire fixation bolt interface. He stated that an upper pre-tension limit of 1250N is to be used(1). Spiegelberg et al also states an upper torque limit of 155 Newton meter (Nm) will cause plastic deformation (stretching) of the wires(41). Davidson et al investigated the best way to achieve adequate pre-tension. He noted that the pretensioners provided by the different companies are inefficient in delivering the required tension. He then compared the efficacy of twisting (as described by Ilizarov) wire bolts to achieve the required pre-tension. Three types of wire fixation bolts, cannulated, slotted and Russian wire fixation bolts, were compared and it was found that the Russian wire fixation bolt was the best at delivering tension of 785 Newton (N) at 45 degrees, 1200 N at 90 degrees and 1695 N at 135 degrees. Compared to the company pre-tensioners that could deliver maximum 1330 N. The other two bolts regularly broke the wires at 90 degrees(10).

Spiegelberg et al advised for wires to be in different planes and on both sides of the ring to increase stiffness(41).

The last and very significant aspect of wires are their orientation (crossing angle) to each other. Fleming et al states that by crossing wires at 90 degrees the axial stiffness is reduced(14) but Podolsky et al stated the opposite in that reducing the wire angles axial stiffness was reduced (and concurrently increased torsional stiffness)(37). Roberts et al supports the findings of Podolsky(38). Having a crossing angle of less than 60 degrees the advantage is to have increased bending stiffness in the plane of the wires but unfortunately risking the bone segment to slide along the plane of the wires. Also, the bending stiffness in the bisector line of the closely crossed wires will be reduced, but this can be nullified by having a half pin in the bisector plane at different level (13, 41).

ii) Half Pins

It has been found that the use of half pins increases stiffness of Ilizarov frames in especially bending and torsional stiffness(5, 13). Though half pins may cause bending if applied in a wrong arrangement(40).

Using hydroxyapatite coated pins will increase pull-out strength(41).

iii) Wire fixation bolt interface

The loss of tension in the wires are mostly due to slippage at the wire fixation bolt interface that holds

the wire to the ring(1, 18). Thus, it is advised to check the wire fixation bolt regularly(13). Mullins et al advised a tightening the wire fixation bolts to a torque of 10 Nm(32). Aronson et al suggested 20 Nm(1). Ring material also influences wire slippage. Slippage being more of a problem with stainless steel rings than with aluminium alloy rings. With alloy rings, the tightened wire fixation bolt will cause an indentation of the ring, preventing slippage. The under surface of the wire fixation bolts have also been roughened in an attempt to prevent wire slippage(30). Gessman et al showed that the newer design TrueLok™ Wire fixation bolts (OrthoFix, Verona, Italy) were also superior in preventing wire slippage(18).

iv) Rings

There are a few parameters to consider when using a ring:

Material

Size

Design (Full, Partial, Arch)

Number of Rings

Ring block concept

Position in relation to the bone segment

The type of material the rings are made of will influence stiffness(42). Taylor Spatial Frame™ (TSF) rings (Smith & Nephew, Memphis, Tennessee, USA) made of Aluminium alloy are thicker than standard Ilizarov rings made of medical grade stainless steel. Thus, TSF rings are more stiff.

The smallest possible diameter applied to the affected limb will be the most stable(3, 9, 13). By reducing the rings diameter by two centimetres, frame stiffness will increase by 70%(17).

Full rings are stiffer than partial or arch type rings(13).

Increasing the number of rings will also increase stiffness(3, 15).

Sarpel et al demonstrated how the use of ring block, two rings around one bone segment, provided the best stiffness, but that one ring can be used to stabilise a bone segment if the appropriate wire and half pin configurations are used(40).

It has been shown how by offsetting the bone segment from the centre of the ring axial stiffness increases, but that torsional stiffness reduces(14, 37). Again, by Bronson et al it was shown that the “near and far” principle of bone segment fixation will lead to a more stable construct. It means that a

ring must be put as close as possible to either side of the fracture/bone defect and as near as possible to the far end of the involved bone segment. Thus, the whole bone segment will be suspended from both ends in the “fracture block” created by the two rings(3).

Also, the distance between two rings, spanning a fracture, should not span a distance of more than sixteen centimetres as torsional stability will be reduced. Otherwise a “dummy ring” (a ring with no wire or half pin attachments) needs to be inserted between the two “functional rings” to stabilize the frame(15). This is not applicable to a ring block spanning an intact bone segment. Hexapod ring constructs with obliquely placed struts also don’t need to follow this “rule”.

v) Connecting Rods

The connecting rods are the parts of the frame that span between the rings. They are required to keep a fixed distance between the rings, to keep the rings perpendicular to each other and to prevent bending and torsional deformity. The classic Ilizarov rods are six millimetre diameter threaded rods, made of medical grade stainless steel. The factors that influence rod stability are:

- the number of rods (more equates to greater stiffness)

- rod thickness (e.g. hollow tube or telescopic)

- the angle the rods are placed at between rings.

Tan et al has showed how increasing the number of rods increases axial and torsional stiffness but not significantly so(42).

The same work by Tan also showed that thicker rods increase stiffness. Fragomen et al holds the same views in his article(15).

The rod angles, for when the classic rods are used, must be perpendicular to the ring. Different rod angles (which leads to greater resistance to torsional stresses) come into play with hexapodal type frame constructs which is outside the scope of this literature review(42).

Ilizarov classically described to use four connecting rods between adjacent rings (39) and most authors will attest to this view(15, 41, 42). The only author who ventured an opinion on the use of the three rods was Podolsky(37).

vi) Miscellaneous

One other factor that influences frame stability is compression of the fracture site(9). This can be achieved by compressing the rings spanning the fracture gap(6). This isn’t always feasible as the

fracture site may be an unstable pattern. Also, it is paradoxical in that the frame is supposed to stabilize the fracture and now the fracture is stabilizing the frame. But as seen in the section on bone healing, there will be a natural increase in fracture gap stiffness as the newly formed callus hardens. Thus, as the frame facilitates the healing response so the healing (stiffening) fracture gap itself will facilitate frame stiffness.

AREAS OF FURTHER RESEARCH

As can be concluded from the above summary the Ilizarov frame has, and still is, being studied extensively. Due to the interplay of the different components on frame stability and stiffness it is difficult, especially in vivo, to assess each component's role in isolation. The large number of in vitro biomechanical studies try and isolate each component and assess its influence on stability. But even then, to translate those individual findings into the complexity of an in vivo frame is always headed by a warning that further research on the clinical significance is indicated. In conclusion, the effect of different rod configurations hasn't been investigated yet. Or at least nothing is available in the published English literature. It is assumed from Ilizarov's original work that four connecting rods, as near to equally spaced around the circumference of the rings, is the standard of care. Even though some studies have looked at an increased number of rods (more than four), none investigated the use of three rods (which is the bare minimum needed for three-dimensional support). Some clinicians prefer the use of three rods as this reduces the complexity of the frame. Also, none of the studies looked at asymmetrical spacing of the rods. This is very much the case in clinical practice, as the rods may need to be moved out of symmetry to account for a wire or half pin that needs to be put in that very position on the ring. This also is the case when an ankle spanning frame is applied and a full ring around the distal tibia needs to be connected to a U-ring around the foot. Symmetrical spacing around the distal tibia ring is impossible as the rods may need to transverse the foot. So, the defined limits of asymmetry are also unknown. This area will be the focus of this research.

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PART B

MANUSCRIPT IN ARTICLE FORMAT

ARTICLE

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Title

The Influence of Different Connecting Rod Configurations on the Stability of the Ilizarov Frame: A Biomechanical Study

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Conflict of Interest

The authors declare that they have no conflict of interest.

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Abstract

Background

The Ilizarov external fixator (IEF) is frequently used in trauma and elective orthopaedics. Many of its biomechanical variables (ring size; wire diameter; wire number; half pins versus wires; etc.) and their influence on stability and stiffness have been investigated. There is however a paucity in the literature regarding the influence of the connecting rod numbers and configurations between the rings on IEF stability.

Objectives

Primarily to compare the stability between four and three rod IEF configurations. Secondly to assess the difference in stability between symmetrical and asymmetrical spacing of the IEF rods.

Methods

A custom jig was designed to facilitate mounting of a basic two ring IEF in a hydraulic press. Controlled centre and off centre (thus simulated bending) axial loading was then applied across the frame. The configurations were loaded up to 4000 Newtons. The frame deformation was plotted and the data was then analysed and interpreted.

Results

Negligible differences were observed between different four and three rod configurations as long as the applied force at the loading point (LP) was within the area of support (AOS) created by the rods. The different four rod constructs were always more stable than the three rod constructs during bending.

Conclusions

There is comparable stiffness between a four rod and a three rod IEF construct as long as the loading point (LP) is within the area of support (AOS) created by the rods. A four rod IEF is stiffer than a three rod IEF in bending.

Key Words

Ilizarov; Stability; Stiffness; Connecting Rods

Introduction

Professor Gavriil Abramovich Ilizarov developed his circular external fixator during the 1950's. Due to the differences in politics between the Russia and the West, his work remained behind the iron curtain until he treated a non-union of a well-known Italian photographer, explorer and alpinist, Carlo Mauri in 1980. After Mauri sang Ilizarov's praises in an article titled "Michelangelo of Orthopaedics", Ilizarov got invited to Italy in 1981 to present his work. This opened the door for the Ilizarov External Fixator (IEF) to be introduced into western medicine and subsequently become an indispensable trauma and elective surgical tool.

It has been well demonstrated using Perren's strain theory[1] that bone healing was influenced by axial force vectors[2-4]. The effect of the other force vectors, e.g. translation, torsion and bending, on bone healing is still uncertain[5].

A high volume of research has been and still is being conducted on the different mechanical aspects of the Ilizarov frame. Most are in vitro studies and of a biomechanical nature. The fine wires were investigated for material type, wire type, thickness, pre-tension, number, planes and angles of convergence[6-15]. The effects of half-pins were investigated[16-18] as well as the wire fixation bolt holding mechanism[6,19,20]. The Rings were studied in regards to material type, size/diameter, design, number used, configuration as well as position in relation to the bone segment[21,22,17,10,23,12,18,24]. Also the influence of the fracture configuration on frame stability has been studied[8,22]. The last component to comment on was the connecting rods that holds the rings in a fixed relationship to each other, which is parallel and fixed in spanning distance. Subsequently the number of rods (four or more), rod thickness and rod angle has been investigated[23,24].

Classically it was described by Ilizarov to use four connecting rods, symmetrically spaced, between adjacent rings and most authors will attest to this view[14,24,23,25]. No research could be found pertaining to the use of four rods versus three as well as to different spacing positions of the rods around the circumference of the IEF rings and its influence on frame stability. At least nothing is available in the published English medical literature.

The primary question we want answered was if there was any difference in stability between four and three rod IEF configurations. Secondly if there was any difference in stability between symmetrically and asymmetrically spaced rod IEF configurations.

Methods and Materials

Two 155 millimetre Taylor Spatial Frame™ (TSF) (Smith & Nephew, Memphis, USA) full rings were used to construct ten basic frame configurations consisting of two rings only. The configurations were divided into two groups. The first group (Group Square - S#) all were constructed using four rods and had five different constructs (S1-5). The second group (Group Triangle - T#), using three rods, also had five different constructs (T1-5). The groups were pairable in design, e.g. S1/T1, S2/T2, S3/T3, S4/T4 and S5/T5 (Figure 1). The rods were of six millimetre threaded medical grade stainless steel (Smith & Nephew, Memphis, USA). The distance between the rings were fixed at fifteen centimetres. The first test sample in each group (S1 & T1) were constructed with the rods equally spaced around the circumference of the rings. Thus S1's rod placement was every ninety degrees and T1's rod placement every hundred and twenty degrees. Then subsequent configurations in each group had the anteriorly placed two rods be moved wider and wider apart. The posterior two rods in the Square group were moved proportionately closer. In the Triangle group the third rod, making up the triangle, was always positioned at the most posterior point on the ring. Thus, the apex of the triangle was always posterior in the Anterior-Posterior (AP) plane. Test samples S3 and T3 both had the anterior two rods positioned on the ring equator with spacing in between of hundred and eighty degrees.

The frames were then loaded into a Zwick 1484 Universal Testing Machine. A custom-made jig was developed for this study so that the frames could be securely mounted in the Zwick Machine. All the frames were then axially loaded at one millimetre per minute up to four thousand Newtons (Figure 2). Previous studies used upper loading values of seven hundred Newtons, far less than what was applied here, due to that representing the downward force of a standing man of average weight[24]. We argued that during normal gait up to 4.45 times body weight could pass through the lower third tibia[26]. Also a high percentage South Africans are generally obese, with more than fifty percent of men and more than sixty percent of women being overweight in 2008[27]. During the centrally directed axial loading tests all five test samples of each group (S1-5 & T1-5) were tested. During the off centre (simulated bending) axial loading test the last test sample of each group (S5 and T5 respectively) wasn't tested due to test samples S4 and T4 already demonstrating severe instability (bending). Bending was only tested in the AP plane, and on the anterior aspect of the ring, as this was the area of interest. This was the area where the anterior two struts were being moved incrementally further apart and thus where the frame would theoretically have increasingly less support and stability. Torsional stress was not tested as we were unable to attain a modification of the custom jig that would convert an axially directed force into a coupled torsional directed force (as was done by Podolsky et al [12]).

We did not use a biological model due to the complexity of recreating a representative model of the in vivo tibia. We felt that any attempt would not be representative and introduce unnecessary variables.

The first and second authors constructed all the frames, using the standard Ilizarov set tools, performed all the tests, after being trained by the Engineering department and analysed the data. Each test was performed only once. Frame deformation, seen as shortening of the set fifteen centimetres between the two rings, was electronically captured by the Zwick machine. The results were plotted by *testXpert IITM* software. The results were then further analysed in *Microsoft Office Excel 365TM*. Descriptive statistics were used to describe the data and no further statistical analysis was performed after discussion with a statistician.

Results

The initial parts of the load-deformation curves varied in no consistent pattern between the different frames. This was seen between the values of zero to five hundred Newtons. We realized that this was due to the different contact points between the Zwick machine, custom jig and the frame components “settling in” as the initial loading pressure was being applied. Afterwards the curves started to show a smooth trend which made interpretation possible.

In some of the samples at the extreme of testing (figure 3) we noticed a sudden dip in the load-displacement curve which was attributed to the rods, being held in the TSF ring rod hole by nuts on both sides, shifting. It is well known that the holes in the classic Ilizarov and the TSF rings’ diameter are more than the six millimetre rods. After the rod settled in a firmer position on the side of the hole the curve quickly returned to its normal overall trend.

After eliminating the initial parts of the curves between zero and five hundred Newtons we zeroed all the curves to start from the same point on the chart so that comparison between test samples could be made.

Centrally Applied Axial force

Like the study performed by Tan et al[24] we also demonstrated that all the frames are more stiff during centrally applied loading than off centred loading (simulating a bending moment). Paired samples S1/T1, S2/T2 and S3/T3 displayed similar load bending curves (Figure 4). There was no significant observed difference between them and their stability didn’t seem to weaken in a specific logical order. There was overlap at different places between the curves of S1, T1, S2 and T2. S3 and T3 did display less stiffness but this was only really apparent nearing forces more than 3000 Newton. What was very apparent was the reduction in stiffness displayed by test samples S4/T4 and even more so by S5/T5. This instability is due to the distance between the anterior two rods being more

than hundred and eighty degrees. All the rods were thus posterior to the ring equator and to the centrally applied axial force loading point (LP). The applied force was thus acting as a bending moment.

Off Centre Applied Axial Force

In these tests the difference between the two test groups became more apparent. All the constructs showed increasing less resistance to bending in a logical ordinal manner (Figure 5). S1/T1 were the stiffest, followed by S2/T2, then S3/T3 and finally S4/T4 being the weakest (to such a degree that the S5/T5 bending tests were abandoned). In the paired groups the four rod test sample was always stiffer in comparison to its three rod counterpart.

Discussion

It is well known that bone healing is influenced by different force vectors that act on it. The beneficial as well as detrimental effects of axial force and frequency (compressive and distractive) have been well investigated, even though there is uncertainty to which one is best[28]. The other force vectors (bending, translational and torsional) are still considered to be detrimental to bone healing[5,10] even though some authors found evidence contradicting this[29]. Due to this current understanding of force vectors on bone healing, the priorities of any fixation device (be that either internal or external) are to neutralise any bending, translational and rotational shear forces whilst at the same time controlling axial forces within the boundaries of the device's design and application purpose. For direct healing, absolute stability (torsional, translational and bending all neutralised) with compression across the fracture gap is required. On the other hand for indirect healing torsion, translation as well as bending must be neutralised but axial forces has to be controlled within the tolerable stress range of the tissue that needs to form. The IEF also needs to deliver on these requirements.

The various IEF components, and each's influence on the different force vectors, has been extensively studied, except for the connecting rod configurations. It is assumed from Ilizarov's original work that four connecting rods, as near to symmetrically spaced around the circumference of the rings, is the standard of care. Numerous authors attest to this view of using four rods[23,25,14,24]. Only Podolsky et al mentioned three rods may be used, although it didn't form part of his investigation[12]. Even though some studies have looked at an increased number of rods (more than four)[24], none investigated the use of three. Some clinicians prefer the use of three rods as this reduces the complexity of the frame. Also none of the studies looked at asymmetrical spacing of the

rods. This is very much the case in clinical practice, as the rods may need to be moved out of a position of symmetry to account for a wire or half pin that needs to be put in that very position on the ring. This also is the case when an ankle spanning frame is applied. A full ring on the distal tibia needs to be connected to a U-ring around the foot. Symmetrical spacing around the distal tibia is impossible as the full and U-rings don't match up in shape.

After comparing the different test samples a few observations could be made by looking at the load-displacement curves.

There seems to be no significant difference between the stability, during central axial loading, of the four and three rod test samples as long as the LP falls within the area of support (AOS) created between the rods (Refer to the schematic of test samples S1/T1 and S2/T2 in Figure 1). This observation is also applicable if the LP falls on the border of the AOS (Refer to the schematic of test sample S3/T4 in Figure 1). Once the LP falls outside the AOS, the same centrally applied force becomes a bending moment and the frame starts to deform. The resulting effect being that the anterior part of the frame is being compressed whilst the posterior part is being distracted, the pivot point being the line between the two anterior rods. This rate of deformation becomes more pronounced the further outside the AOS the LP falls. If the bone segment is seen as the axis of the LP, then to be sure that the LP is within the AOS there has to be a visible rod on each side of the bone segment on both the AP and lateral views. The "rule of twos", as described by Rozbruch and Ilizarov, is a well-known guide to IEF construction[25]:

- 2 centimetres between skin and frame
- 2 rings per bone segment
- 2 point of fixation per ring
- 2 x 2 (thus 4) connecting rods between rings
- Both ends (thus 2) of the bone segment must be stabilized - the "near and far" principle
- 2 planes of fixation per ring

Due to the test findings, it could be considered adding to the rules "*rods on 2 sides on 2 views (one on either side of the bone segment)*". This would be most relevant in the tibia where the bone is eccentrically placed within the lower leg and the rings. Care should be taken to keep the tibia within the AOS of the frame.

The off centre axially applied (simulated bending) tests gave more insight into the difference in stability between the four and three rod test samples. Between the different test pairs, S1/T1, S2/T2, S3/T3 and S4/T4, the four rod test sample was always more resistant than the three rod test sample to bending. Since the LP was outside the AOS from the onset the load-displacement curves were worse than for the corresponding centrally loaded test pair. The reason for the square four rod test

samples being more resistant to bending was likely due to the two posterior rods that provided more rigidity than the single posterior rod of the triangular three rod test samples.

All the test samples had a curved load-displacement graph. Even the test samples loaded centrally with the LP falling within the AOS. This means that with any frame, even sturdily built, following correct placement principles of all the components as described by the literature, that there will be a very minor shortening of the distance between the rings spanning the fracture site on each step. This indicates that the rods has to be bulging sideward, within its elastic capacity, during the weight bearing phase of the gait cycle. Does this actually happen in vivo? Maybe not as the smooth wire and half pins are likely absorbing the axial force. Since this study didn't apply the axial forces through a bone-wire interface we can only speculate.

Study limitations

There are limitations to our study, foremost it being an in vitro study. Manipulating only one isolated variable in a biomechanical study will never be a proper substitute for a randomized control clinical trial. But it is still a good and safe departure point for further research. Also we didn't test posterior, lateral or medial bending. Rotational stability was also not assessed. Critique may also be levered at the manipulation of the data to make the load-displacements graphs overlap and thus be more comparable. Since it was never the aim of the study to gather *absolute values* for stiffness but rather to *compare trends* this may well be considered a minor weakness. Another limitation was that only a single ring size (160 millimetre) was used during testing. With smaller ring sizes (e.g. 80 millimetre), the construct's stiffness may be so high that the spacing of the rods may be irrelevant.

Future Research

Future investigation may further exploit the LP in the AOS, the "rods on 2 sides on 2 views", principle. By constructing further test samples with asymmetrically spaced rods, the LP could be shifted to always stay within the AOS and see if the load-displacement curves' trend changes. Torsional stiffness also needs to be investigated between different rod configurations. The same concept may also be tested with a biological model, with a standardised wire or half pin configuration (to remove confounding factors) to see if the bone segment can be substituted for the LP.

Conclusion

There is comparable stiffness between a four and a three rod Ilizarov External Fixator during axial load as long as the Loading Point remains within the Area Of Support (formed by the rods). A four rod Ilizarov External Fixator is stiffer in bending than a three rod Ilizarov External Fixator.

LIST OF FIGURES

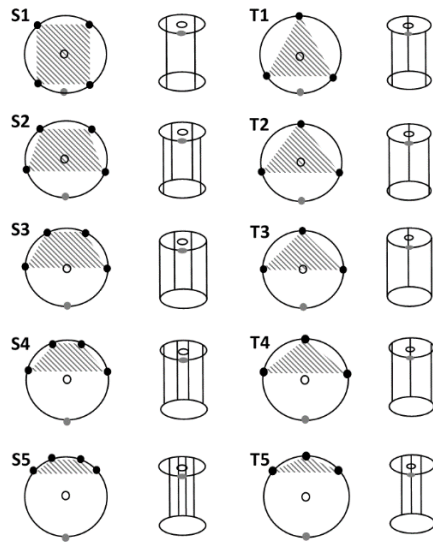


Fig 1 Two paired test groups consisting of four (Square - S#) and three (Triangle - T#) rod configurations. The solid black dots represent rod positions on the rings. The greyed out area represents the area of support (AOS) formed between the rods. The black circle represents the centre loading point (LP). The grey circle represents the off centre LP.



Fig 2 A four rod test sample mounted in the custom jig before testing in the Zwick 1484 Universal Testing Machine

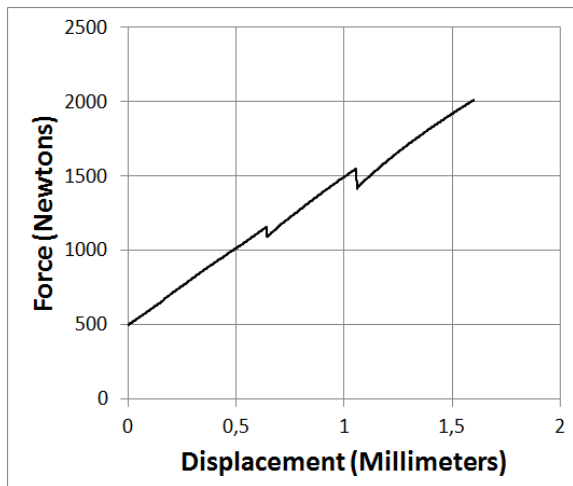


Fig 3 A graph depicting the sudden decreases in load as the rods shift in the ring holes

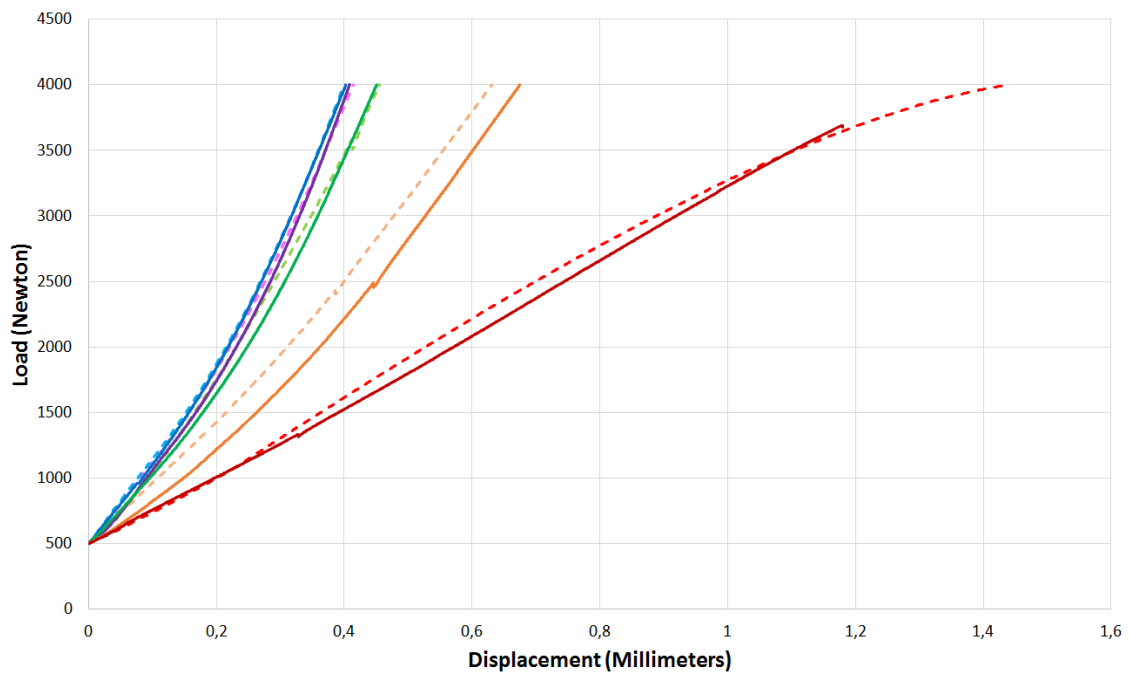


Fig 4 The load-displacement curves during centre axial loading

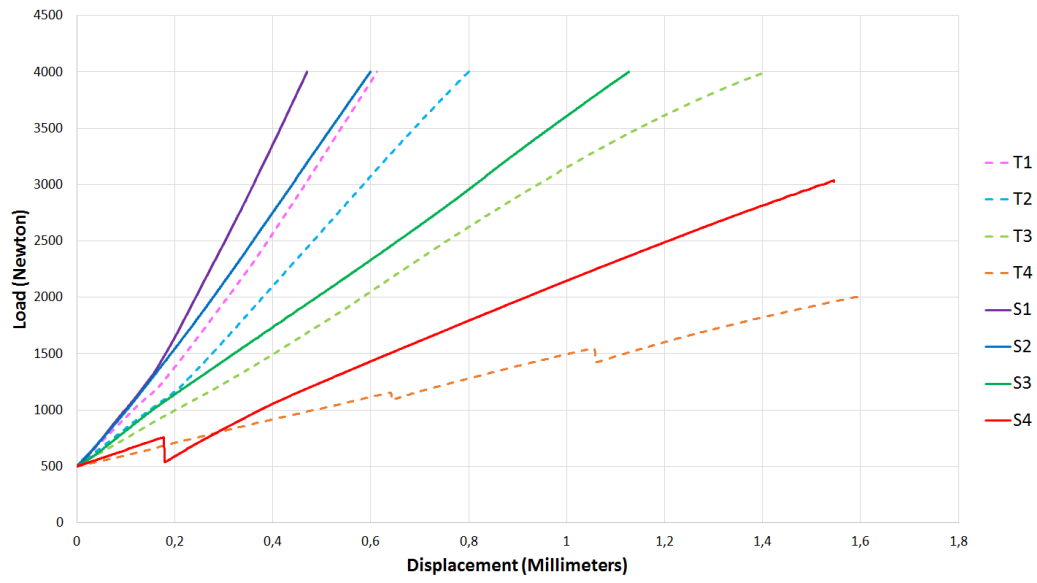


Fig 5 The load-displacement curves during off centre axial loading (simulated bending)

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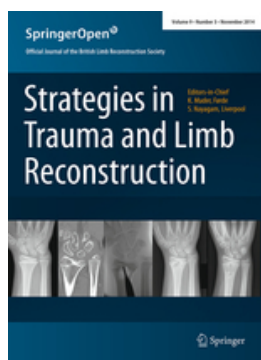
PART C

ADDENDA

Relevant journal information and
instructions to authors

Orthopedics Home > Medicine > Orthopedics

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Strategies in Trauma and Limb Reconstruction

Editor-in-Chief: K. Mader; S. Nayagam

ISSN: 1828-8928 (electronic version)

Journal no. 11751



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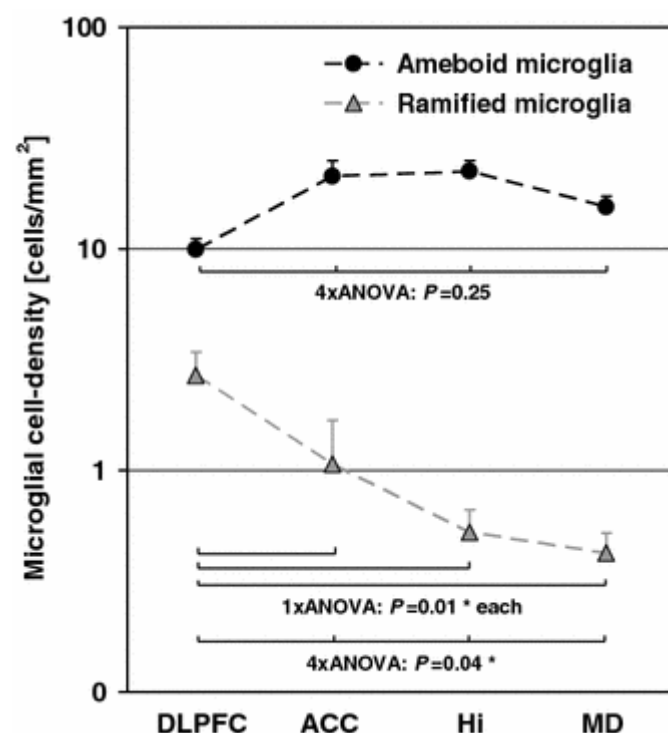
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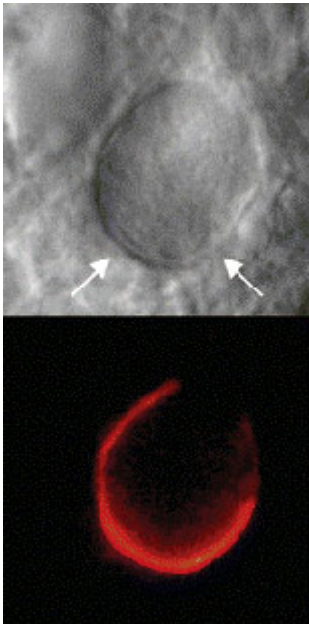
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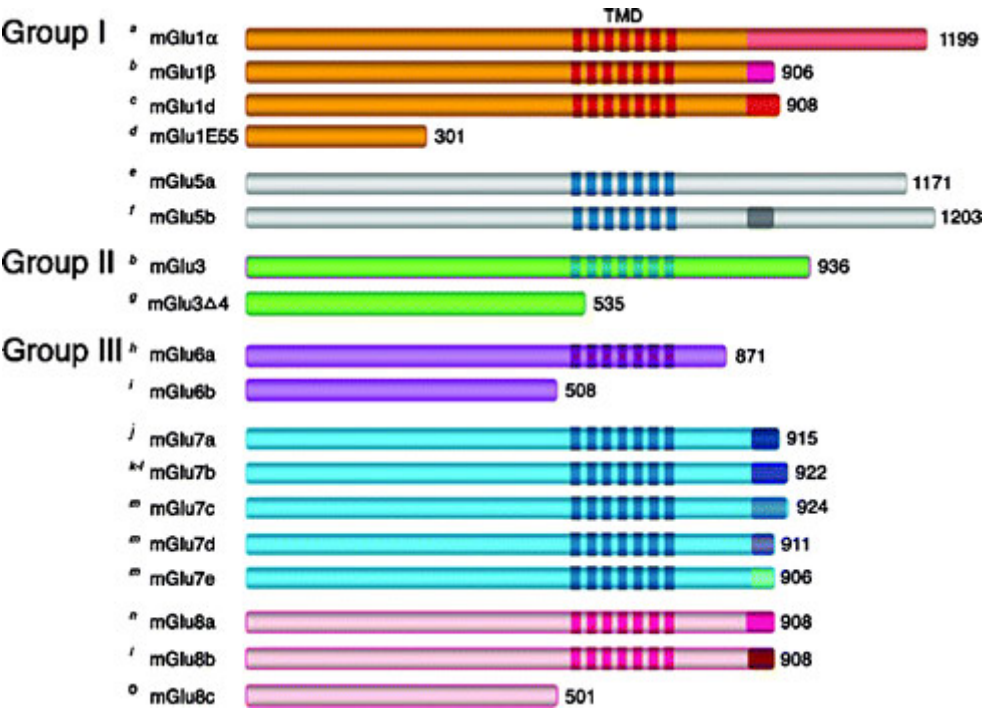
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Research Proposal

RESEARCH PROTOCOL

The influence of different connecting rod configurations on the stability of the Ilizarov frame.

Investigators: Gerhard Thiar; Sudesh Sivarasu; Saadiq Gasant; Sithombo Maqungo; Graham McCollum; Steve Roche; Maritz Laubscher

STUDY BACKGROUND

The Ilizarov frame was designed by Dr Gavriil Abramavich Ilizarov during the nineteen fifties to overcome the short comings of monoplanar external fixators(1). Due to the mechanical nature of a monoplanar external fixator a cantilever effect of motion is generated at the fracture site. Studies in bone healing has proven that any shear type forces at the healing fracture site has negative outcomes in regards to union(2). Controlled axial loads are known to stimulate union. Dr. Ilizarov thus developed a circular fixator system that countered lateral bending and rotational moments at the fracture site and that provided a conduit for controlled axial forces. It consists of multiple rings around the limb connected to each other with threaded rods and with the rings connected to the bone through a combination of pins or wires. The system was accepted by the orthopaedic community as a valid treatment modality for specific fracture patterns and is being used worldwide. Groote Schuur Hospital also uses the Ilizarov frame.

Numerous studies have been done on the biomechanics of the Ilizarov frame. The bulk of them focused on the ring-pin/wire-bone interface and how different configurations will alter frame stability(3, 4). But the effect of the different connecting rod configurations hasn't received as much attention.

The purpose of this study is to investigate the change in stability of the Ilizarov frame when the rods (which are usually spaced in a symmetrical pattern around the ring) are spaced in different configurations of asymmetrical patterns. We will also investigate the difference in stability using three or four rods. The investigations will be done in a biomechanical laboratory using a machine that can apply controlled and readable forces to Ilizarov frames, while the stability of the construct will be measured. No cadaveric tissue, animal or human patients will be used. This is purely a biomechanical study.

The significance of this investigation is that asymmetrical placement of rods are currently being used. This happens due to different fracture patterns which forces the surgeon to place

pins/wires in specific positions on the circular ring. Thus the connecting rod has to be moved (out of its symmetrical position) to a different position to accommodate the pins/wires. Some surgeons even use three rods and not the classic four as described by Dr. Ilizarov. This is done with no one really knowing if there is a significant difference in frame stability and if this will compromise union rates.

The outcome of this study has the potential to change our clinical practice in regards to how the frames are applied and built. We will be able to contribute to the international body of literature on the topic. Future studies may use this information to correlate union rates of different frame configurations that have been applied in clinical practice. We might then be able to optimize frame stability for union which will benefit our patients.

RELEVANCE OF THE STUDY

The relevance of this study is to determine if the current clinical practice of building the Ilizarov frame using three rods or four, with any chosen pattern of inter rod spacing, has an impact on frame stability.

STUDY HYPOTHESIS

The asymmetrical spacing of connecting rods in an Ilizarov frame compromises frame stability.

Four rods are more stable than three rods.

STUDY POPULATION

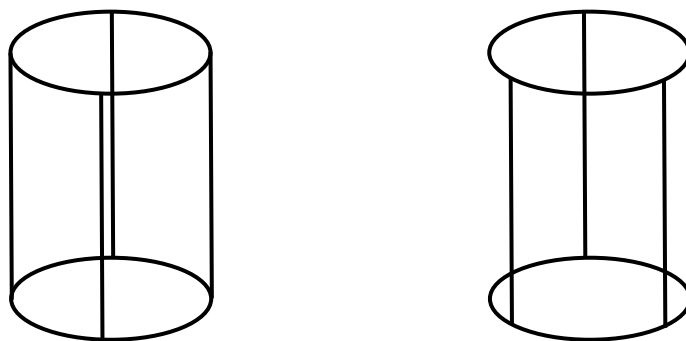
None.

STUDY DESIGN

Biomechanical study

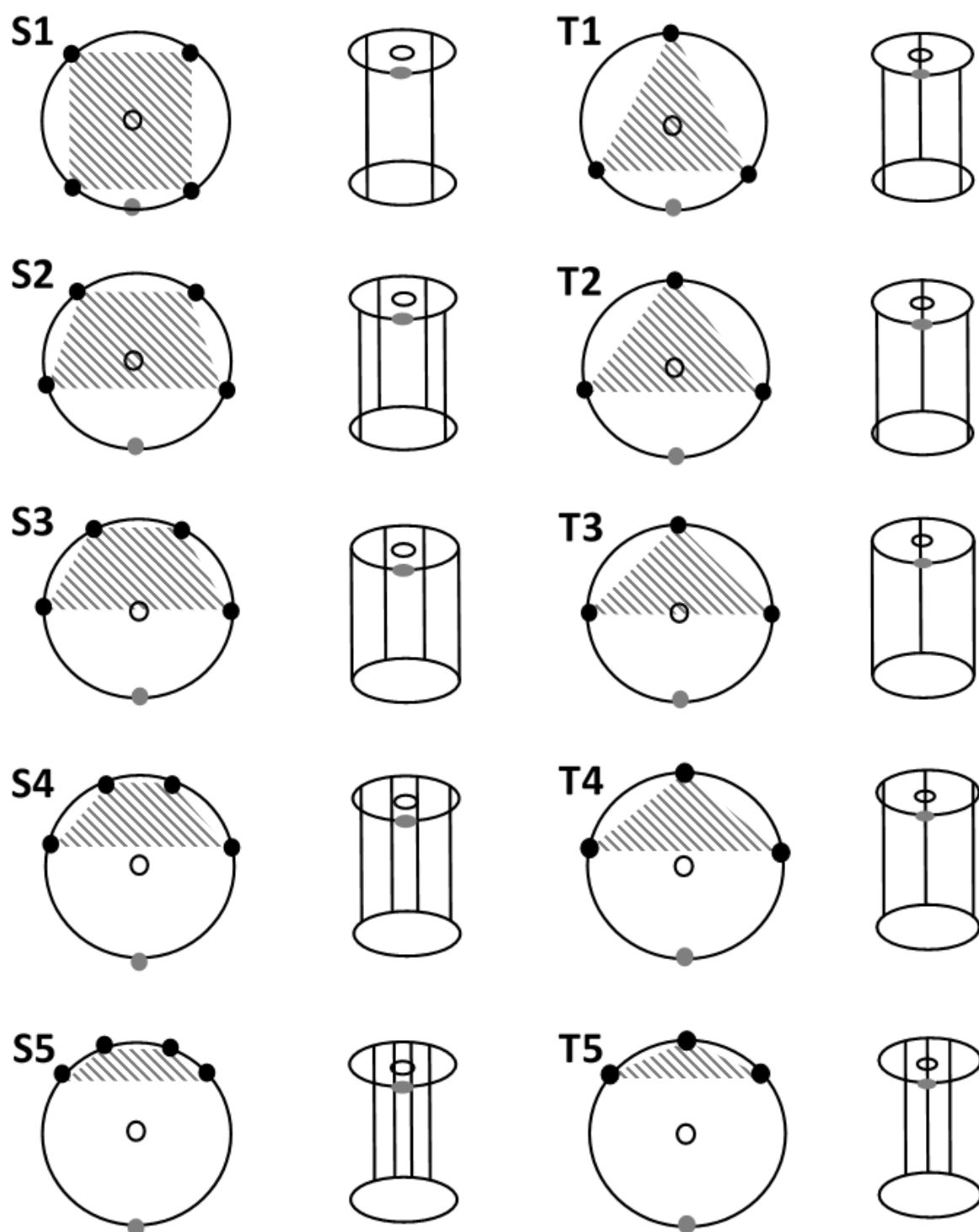
STUDY METHOD

Multiple Ilizarov frame structures (comprising two rings only) will be built using symmetrical and asymmetrical three and four rod interconnecting configurations:



By keeping the base design simple most of the uncontrollable (and thus immeasurable) variables are kept to a minimum.

The following configurations are to be tested (Rod configuration placement as seen from above):



The frames will be tested in a controlled engineering laboratory with a machine that will exert controlled measurable forces in axial, rotational and lateral bending moments. The amount of frame deformity will be measured. The results will be analyzed by a statistician.

ANALYSIS OF THE STUDY

The following parameters will be investigated:

- What force will deform the different frame designs in the three planes of motion (Axial, Rotational and Lateral bending) on all frames tested
- Symmetrical three rod (triangle) VS symmetrical four rod (square) frame stability
- Symmetrical four rod (square) frame stability VS trapezoidal (asymmetrical rectangle) rod placement stability
- Symmetrical three rod (triangle) frame stability VS scalene (asymmetrical triangle) rod placement stability

REPORT OF THE FINDINGS

Results will be submitted for publication in peer review journals. Results will also be discussed at national or international orthopaedic conferences, research or faculty meetings.

ETHICAL CONCERNS

Smith and Nephew, which holds the patent rights on the Ilizarov frame, will provide the frame components and help to cover extra costs needed for the study. Thus, Groote Schuur Orthopaedic Department won't be liable for any expenditures, and will also not be involved in the study method or result interpretation.

BUDGET AND FUNDING

Existing resources will be used to assist in the study as far as possible to minimize cost. The study will be conducted by the main author with the help of the Department of Biomedical Engineering from the University of Cape Town. The co-investigators from the Department of Biomedical Engineering have offered their assistance free of charge to assist in the design as well as the interpretation of results. We would however require help from a mechanical engineer to adapt the testing rig to fit the frames. We would also require the engineer's assistance with the actual testing and measurements.

Furthermore, we would require funding for the items needed to build the frame. Because metal fatigue in second hand components will affect our results, we will require new components for the testing.

Funding will therefore be required as followed:

A) Ilizarov frame components

14 different configurations are to be built. 7 containing 3 rods and another 7 containing 4 rods.

- a. 8x 155mm full TSF rings (the rings can be reused)
- b. 49x 150mm threaded rods (the rods will be tested until failure)
- c. 32x nuts

B) The mechanical testing rig has to modified to fit onto the Ilizarov frame ends.

C) A mechanical engineer must be hired at a rate of R160 per hour for about 100 hours of work. Thus R16 000.

We would therefore like to request funding from (Smith and Nephew) / (SAOA) towards this project. We feel that Smith and Nephew would also be able to benefit from the results of our research on their implants.

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3. Tan B, Shanmugam R, Gunalan R, Chua Y, Hossain G, Saw A. A Biomechanical Comparison between Taylor's Spatial Frame and Ilizarov External Fixator. Malaysian orthopaedic journal. 2014;8(2):35-9.
4. Sarpel Y, Gulsen M, Togrul E, Capa M, Herdem M. Comparison of Mechanical Performance Among Different Frame Configurations of the Ilizarov External Fixator: Experimental Study. The Journal of Trauma: Injury, Infection, and Critical Care. 2005;58(3):546-52.

Oxford Centre for Evidence-Based Medicine 2011 Levels of Evidence

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Question	Step 1 (Level 1*)	Step 2 (Level 2*)	Step 3 (Level 3*)	Step 4 (Level 4*)	Step 5 (Level 5)
How common is the problem?	Local and current random sample surveys (or censuses)	Systematic review of surveys that allow matching to local circumstances**	Local non-random sample**	Case-series**	n/a
Is this diagnostic or monitoring test accurate? (Diagnosis)	Systematic review of cross sectional studies with consistently applied reference standard and blinding	Individual cross sectional studies with consistently applied reference standard and blinding	Non-consecutive studies, or studies without consistently applied reference standards**	Case-control studies, or "poor or non-independent reference standard**	Mechanism-based reasoning
What will happen if we do not add a therapy? (Prognosis)	Systematic review of inception cohort studies	Inception cohort studies	Cohort study or control arm of randomized trial*	Case-series or case-control studies, or poor quality prognostic cohort study**	n/a
Does this intervention help? (Treatment Benefits)	Systematic review of randomized trials or <i>n</i> -of-1 trials	Randomized trial or observational study with dramatic effect	Non-randomized controlled cohort/follow-up study**	Case-series, case-control studies, or historically controlled studies**	Mechanism-based reasoning
What are the COMMON harms? (Treatment Harms)	Systematic review of randomized trials, systematic review of nested case-control studies, <i>n</i> -of-1 trial with the patient you are raising the question about, or observational study with dramatic effect	Individual randomized trial or (exceptionally) observational study with dramatic effect	Non-randomized controlled cohort/follow-up study (post-marketing surveillance) provided there are sufficient numbers to rule out a common harm. (For long-term harms the duration of follow-up must be sufficient.)**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning
What are the RARE harms? (Treatment Harms)	Systematic review of randomized trials or <i>n</i> -of-1 trial	Randomized trial or (exceptionally) observational study with dramatic effect			
Is this (early detection) test worthwhile? (Screening)	Systematic review of randomized trials	Randomized trial	Non-randomized controlled cohort/follow-up study**	Case-series, case-control, or historically controlled studies**	Mechanism-based reasoning

* Level may be graded down on the basis of study quality, imprecision, indirectness (study PICO does not match questions PICO), because of inconsistency between studies, or because the absolute effect size is very small; Level may be graded up if there is a large or very large effect size.

** As always, a systematic review is generally better than an individual study.

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